Second Supplemental Case-Specific Report of
Douglas H. Grier, M.D.
Barbara Smith (DOB 3/23/41)

I previously issued reports in this case on 2/13/17 and 6/22/19. Since that time, I have continued to review published medical literature pertinent to this case, as well as subsequently received medical records, depositions, and other materials that have been obtained and produced, the most pertinent of which are referenced below. I stand by the opinions set forth in my prior reports in this case and incorporate those reports in this second supplemental report by reference. I have also had the opportunity to examine Ms. Smith a second time, and have summarized my findings from that examination in this report.

Her medical records reveal that cystoscopic removal under anesthesia by Mathew Forsyth, MD on 11/4/19 was unsuccessful. She underwent bladder mesh excision by Jeffrey Wheat, MD on 1/03/20. The approach was suprapubic tract access to the bladder with laser of the exposed mesh under direct cystoscopic visualization. The procedure was prolonged by technical difficulties, taking 2 hours. The area of mesh exposure was excised using the laser, which is directly contributory to the formation of a vesicovaginal fistula developing post operatively. Post-operative surveillance cystoscopy on 1/30/20 revealed a single mesh fiber remaining, and what was presumed to be urge incontinence, but no fistula. The patient noted that she rarely voids, but rather, leaks continuously.

Cystoscopy performed by Dr. Wheat on 3/4/20 revealed no visual evidence of bladder exposed mesh but a pinpoint vesicovaginal fistula. The patient's fistula repair was placed on hold due to her continuous tobacco usage of ½ to 1 pack per day. The patient has a 51 pack year history of smoking and did stop in May 2020.

On 6/24/20 Jeffrey Wheat, MD performed a vaginal approach vesicovaginal fistula repair of a very small anterior wall vaginal fistula to the floor of the bladder that could not be cystoscopically visualized or cannulated with a wire at the time of surgery. Two small fistulas were identified after a U flap incision was made and no mesh was identified at the area of fistula. The procedure was completed with absorbable suture and catheterization was performed for two weeks post operatively.

Ms. Smith had a follow-up visit with Dr. Wheat on 4/22/21 following intravesical Botox injection he performed on 2/11/21, which was noted to have provided no benefit. She reported that her urinary leakage was worse than ever. She reported voiding frequently, but straining to void and only voiding small amounts. Vaginal exam showed a normal urethra, with no masses, tenderness, or lesions. The vagina was atrophic and there was a small pit approximately 1 cm proximal to the bladder neck, which was leaking a small amount of clear fluid while her bladder was full during cystoscopy. Spot images from fluoroscopy used during urodynamics were interpreted as showing a small fistula posterior to the urethra, through which urine was leaking. FUDS was performed that showed no first sensation or desire and no strong desire at 550 ml.

There was no uninhibited contraction. The bladder was compliant. The Valsalva leak point pressure was 120 cm H2O, and there was apparent leakage from the fistula posterior to the urethra. There was no voiding pressure at 550 ml; voiding was exclusively via Valsalva. The bladder wall was smooth, but the fistula was noted posterior to the urethra. At the base of the trigone, just posterior to the bladder neck, there was a pit on which there was a small calcification with exposed mesh. The diagnosis was vesicovaginal fistula and urinary retention from atonic bladder with Valsalva voiding. Dr. Wheat expressed concern that any future fistula repair would be doomed to failure in light of her Valsalva voiding, which would cause a high risk of breakdown of the repair site. Dr. Wheat preferred an autologous fascial sling over a Martius flap, as it would sit closer to the bladder neck. He also recommended that she avoid Valsalva voiding and instead try intermittent catheterization. (MRITTER_RPD_00008-10.)

Supplemental Independent Medical Examination

Ms. Smith presented for examination on 11/17/20 in my office in Edmonds, Washington. I last saw and examined Ms. Smith on 2/1/17. At the time of that initial visit, the patient had not been evaluated or treated for her urinary tract infections or pelvic complaints for many months prior. The patient was found to have a urinary tract infection on that visit and was advised to seek care at Kaiser Portland as soon as possible. During the examination on 11/17/20, she stated that she is much improved since that 2017 visit, although she underwent a cystoscopy on 11/04/19 and 11/29/19 with the finding of two 5 mm areas of mesh exposure on the bladder floor.

She describes continuous urinary incontinence with only rare ability to initiate a stream of urine. The patient is pad dependent around the clock and has urgency and frequency of urination. She no longer goes to the toilet to void, but rather drains into pads. When asked to provide a urine specimen she was unable and stated that she cannot spontaneously void. The patient was five months out from a vesicovaginal fistula repair that she does not feel improved her incontinence. She does not complain of pelvic or vaginal pain and has stopped using vaginal estrogen cream as prescribed. The apparent eventual plan would be for placement of a pubovaginal sling to obstruct her urethra and make her permanently catheter dependent so as to end the incontinence. The patient apparently has not recorded any bladder infections since her latest surgery in June and urinalysis at the time of her examination confirms the absence of infection.

Vital signs: Temperature 97.9F, pulse 82, O2- 97%, B/P 146/84
Bladder Ultrasound Scan 101 ml
Urinalysis: Yellow/clear ph 7, Glucose negative SG 1.015, Blo-trace intact, Leukocytes small, Pro-trace, few bacteria, 3-5 RBC's, 5-10 Epi's, 3-5 WBC's
Physical Examination: Female chaperone present throughout the examination
Well-nourished moderately obese female in no acute distress
Abdomen: without organomegaly, guarding, or distention. No suprapubic distension or tenderness

Pelvic examination: Normal introitus without vaginal prolapse on straining. Moderate vaginal mucosal thinning and atrophy. Grade one cystocele on straining with continuous urine leakage not visualized emanating from the urethra. No urethral hypermobility with Valsalva straining. Palpation and bimanual examination reveals the absence of tenderness or pain in contrast to her previous examination in 2017. The posterior wall of the vagina was intact with a moderate to large amount of hard stool in the rectal vault. The vaginal length has been foreshortened by multiple surgeries to approximately 7 cm. The vaginal apex is well supported and no visible or palpable mesh is noted either anterior or posteriorly. The area of discomfort during the last examination in 2017 was the central anterior wall which is now non-tender to distraction. The source of urinary leakage was not apparent, however it was not emanating from the urethra. Palpating the area of the urethra to the obturator foramens bilaterally revealed no exposure of the TVT-O midurethral sling, which appears to be providing urethral continence. My suspicion was there was yet again a vaginal wall bladder fistula that was unsuccessfully repaired 5 months earlier. Studies to identify the source of leakage would be a cystogram, cystoscopy with instilled dye, and urodynamics to confirm my impression of a poorly compliant bladder. I was not authorized to perform any invasive testing that would help identify the patient's current bladder dysfunction.

Plaintiff's expert witness, Dr. Daniel Elliott, performed a second medical examination of Ms. Smith on October 10, 2020, and reported that she complained of severe symptoms consistent with stress urinary incontinence . She denied any current symptoms of overactive bladder or pelvic organ prolapse. Dr. Elliott reported that she complained of left lower quadrant pelvic pain, vaginal pain with activities of daily life such as standing and walking. Dr. Elliott's examination revealed that palpation of the left lower quadrant was painful (VAS = 5). He found mild vaginal atrophy that he said was consistent with her age. Palpation throughout the vagina was non-tender, and he noted palpable mesh and scarring on the posterior aspect of the vagina at the introitus. He found no pelvic organ prolapse, and mild urethral hypermobility with no SUI noted, though he noted her bladder was empty. Dr. Elliott opines that Ms. Smith has "severe left lower quadrant pelvic pain that has been unchanged by the implantation of the Prolift meshes," severe—near total—stress urinary incontinence, and bladder mesh erosion from the anterior Prolift causing bladder stone formation and recurrent UTIs. Dr. Elliott also notes that, "[a]s a consequence of the extremely thin tissue between the urothelium and the vaginal epithelium caused by the Anterior Prolift mesh, Ms. Smith has a predisposing susceptibility to recurrence of mesh erosion from Prolift and another fistula that are likely to recur in the future."

Fistula, Erosion, and Urinary Problems

It is unknown when Mrs. Smith developed a bladder erosion. Thus, one cannot, in my opinion, reliably opine that Mrs. Smith experienced urinary tract infections because of the bladder erosion. As I noted in my earlier reports, urinary tract infections are very common. They can be caused by vaginal atrophy, which is a condition that both Dr. Elliott and I observed during our examinations in late 2020.

Where true bladder erosions occur, they are not caused by any alleged defect in the Prolift or TVT-O devices. Mesh erosions typically occur due to either surgeon factors or patient factors, or a combination of the two. Here, Mrs. Smith's smoking history, more likely than not, contributed to her erosion, as erosions occur more frequently in smokers.[1] Mesh erosions are well-known potential complications of any incontinence or prolapse surgery utilizing a mesh graft. Erosions, exposures, or extrusion of mesh in connection with prolapse repairs were well-reported in the published medical literature regarding prolapse treatment prior to Mrs. Smith's implant surgery.[2] Ethicon also warned of the risk of mesh erosion in the Prolift and TVT-O IFUs and in the Prolift Surgeon's Resource Monograph.[3]

A fistula is "an abnormal communication among the genitourinary tract, the gastrointestinal tract, and the vagina or perineum" and fistulae have been described in the medical literature for the past several thousand years."[4] Fistula is a well-known potential occurrence with pelvic surgeries. In North America, the most common cause of vesicovaginal fistulas is bladder injury during hysterectomy.[5] The IFUs for the TVT-O and Prolift devices each warn about the possibility of fistula, but the occurrence of fistula following the use of these devices is rare. Ethicon also discussed the possibility of fistula formation in its professional education materials.[6] In addition, Dr. Wheat warned Ms. Smith during his 11/29/19 office visit that treatment of the bladder erosion could result in a fistula. It is my opinion that Mrs. Smith's smoking history, more likely than not, contributed to the development of both her mesh erosion and consequently, her fistula. It has been reported that fistulas caused by mesh erosion are more frequent in smokers.[7] Any "predisposing susceptibility" to recurrence of mesh erosion (as opined by Plaintiff's expert Dr. Elliott) is, in my opinion, indicative of her poor tissue quality resulting from smoking, prior surgical history, and other conditions, and not caused by her mesh implants.

The recently published literature discussed below further supports my opinions that the TVT-O and Prolift devices are not defective, and were safe and effective treatments for Mrs. Smith's stress urinary incontinence and pelvic organ prolapse, respectively. The low rates of complications noted in these articles further support my opinion that the mesh used in the TVT-O and Prolift devices is safe and effective, and the mesh used in those devices does not contain any inherent characteristic that renders the devices defective. The TVT-O and Prolift devices

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[1] Sørensen LT, Wound Healing and Infection in Surgery. Arch Surg. 2012;147(4):373-383; Kokonali MK, et al., Risk factors for mesh erosion after vaginal sling procedures for urinary incontinence. Eur J Obstet Gynecol and Reprod Biol. 2014 Jun;177:146-50; Lowman JK, et al., Tobacco use is a risk factor for mesh erosion after abdominal sacrocolpopexy. Am J Obstet Gynecol 2008;198:561.e1–561.e4.

[2] Dietz HP, et al., Mechanical properties of urogynecologic implant materials. Int Urogynecol J. 2003;14:239–43; Iglesia CB, et al., The Use of Mesh in Gynecologic Surgery. Int Urogynecol J. 1997;8:105–15.

[3] Prolift Surgeon's Resource Monograph, ETH.MESH.03460813; Prolift +M IFU, ETH.MESH.01595614.

[4] Rogers RG and Jeppson PC, Current Diagnosis and Management of Pelvic Fistulae in Women. Obstet Gynecol. 2016 Sep;128(3):635-50.

[5] Hadley HR, Veiscovaginal fistula. Curr Urol Rep. 2002 Oct;3(5):401-7.

[6] Gynecare Prolift Pelvic Floor Repair Systems presentation, ETH.MESH.07201006; Prolift Surgeon's Resource Monograph, ETH.MESH.03460813.

[7] Sørensen LT, Wound Healing and Infection in Surgery. Arch Surg. 2012;147(4):373-383

are not unreasonably dangerous; the benefits of the devices' designs outweighed the risks of the designs. Ms. Smith's alleged injuries were not caused by a defect in the TVT-O or Prolift devices.

Sun and colleagues conducted a 10-year prospective study comparing the outcomes of patients receiving TVT-O and TVT-Secur devices and found no significant difference in objective and subjective cure rates between the two devices. Both the TVT-O and TVT-Secur groups experienced significantly improved quality of life.[8]

In 2020, Dr. Stephanie Glass Clark and colleagues published the results of their combined secondary analysis of data from the SISTEr and TOMUS trials to evaluate the effects of four different SUI surgeries on 2-year post-operative sexual function. The study included 924 women, 249 of whom had an autologous fascial sling, 239 of whom had a Burch procedure, 216 of whom had a retropubic mid-urethral sling, and 220 of whom had a trans-obturator mid-urethral sling. The authors found that there was no significant difference in mean PISQ-12 scores between 12 months and 24 months, and that there was a clinically important improvement in PISQ-12 scores over the 24-month post-operative period for all treatment groups.[9]

Dr. Abigail Ford and colleagues conducted a review of the literature looking at the safety and efficacy of mid-urethral slings, the results of which were published in 2019. The aim of their review was "to detail the background to SUI which has led to the development of MUS, to highlight the issues surrounding the use of mesh under the current climate of mesh controversies and to provide an update on current evidence on the use of MUS." The authors concluded based on their review that "[t]he overall rates of complications are low including those associated with the use of mesh implants. When compared to other continence procedures, MUS is equally effective in regard to cure but has lower rates of complications and more favorable outcomes." The authors also noted that "[m]ost, if not all, major international societies devoted to treating SUI . . . have all issued statements supporting the use of MUS as the preferred first-line surgical treatment for SUI." They also noted that mesh mid-urethral slings seem to offer, in many aspects of patient recovery and post procedure complications rates, a safer approach to SUI treatment than alternative options such as autologous fascial slings and Burch colposuspension procedures.[10]

Dr. C. Emi Bretschneider and colleagues published a study in 2021 that used data from a national database from 2010 to 2018 evaluating the prevalence of mid-urethral sling revision and fascial slings and their trends over time. They observed that of 32,657 sling procedures, 268 were fascial slings and the rest were mid-urethral slings, suggesting to the researchers that

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[8] Sun Z, et al., Comparison of Outcomes Between Single-Incision Sling and Transobturator Sling for Treating Stress Urinary Incontinence: A 10-year Prospective Study. Neurourol Urodyn. 2019 Sep;38(7):1852-1858.

[9] Glass Clark SM, et al., Effect of Surgery for Stress Incontinence on Female Sexual Function. Obstet Gynecol. 2020 Feb;135(2):352-360.

[10] Ford AA, et al., Midurethral slings for treatment of stress urinary incontinence review. Neurourol Urodyn. 2019 Aug;38 Suppl 4:S70-S75.

mid-urethral slings remain the preferred procedure for treatment of SUI. They also observed that the overall rate of sling revision was only 0.75% over the eight-year study period.[11]

A manuscript recently accepted for publication in *The Journal of Urology* and authored by White and colleagues studied prospective parallel cohorts of patients treated with either single-incision Solyx sling or a multi-incision trans-obturator Obtryx sling. There were 140 patients in the trans-obturator sling group and 141 in the single-incision sling group. The researchers found that in both treatment groups, there was a significant improvement in PISQ-12 scores from baseline to 36 months, indicating the patients had better sexual function following the surgeries. Although the TVT-O was not used in this study, the study nonetheless supports the safety of slings like the TVT-O, as the TVT-O and Obtryx slings are both trans-obturator mid-urethral slings made of Type I polypropylene mesh.[12]

Leron, et al. conducted a long-term study that included outcomes for 58 patients who underwent Prolift procedures and found no significant complications during the procedures or postoperatively at a mean length of follow-up of 9.1 ± 0.59 years.[13]

The complications experienced by Mrs. Smith were not caused by alleged defects in the Prolift or TVT-O devices. The devices were not defectively designed. The devices' benefits outweighed the risks in appropriately selected patients, and the devices were state of the art.

I hold these opinions to a reasonable degree of medical and scientific certainty, and I incorporate by reference in this report the opinions set forth in my February 13, 2017 and June 22, 2019 reports in this case, my general report regarding the TVT-O sling and Prolift device served in this litigation, as well as my general deposition testimony regarding the TVT-O sling and Prolift device. I reserve the right to supplement this report upon the receipt of additional information, if necessary.

Dated: 7/26/2021

Douglas H. Grier, M.D.

[11] Bretschneider CE, et al., Rates of Sling Procedures and Revisions—A National Surgical Quality Improvement Program Database Study. Female Pelvic Med Reconstr Surg 2021 Jun 1;27(6):e559-e562.

[12] White AB, et al., Female Sexual Function following Sling Surgery: A Prospective Parallel Cohort, Multi-Center Study of the Solyx Single Incision Sling System versus the Obtryx II Sling System (FDA-Mandated 522 Results at 36 Months). J Urol. 2021 May 6;101097JU0000000000001830.

[13] Leron E, et al., Long-term outcome (5-10 years) after non absorbable mesh insertion compared to partially absorbable mesh insertion for anterior vaginal wall prolapse repair. Int Braz J Urol. Nov-Dec 2019;45(6):1180-1185.